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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,559	11/27/2000	Wolf-Georg Forssmann	P65315US0	8027

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	27

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/509,559	FORSSMANN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 10 February 2003 (Paper No. 26) has been entered in full. Claims 1-18 were cancelled. Claims 19-29 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection of claim 4 as set forth at pages 3 of the previous Office Action (10 October 2002, Paper No. 24) is *withdrawn* in view of the amendment (10 February 2003, Paper No. 26).

The rejection of claims 1-4 and 12 under 35 USC 101 as set forth at pages 3-4 of the previous Office Action (10 October 2002, Paper No. 24) is *withdrawn* in view of the amendment (10 February 2003, Paper No. 26).

The rejection of claims 1-3, 9, 11, 12 and 14 under 35 USC 112, first paragraph, scope of enablement, as set forth at pages 4-6 of the previous Office Action (10 October 2002, Paper No. 24) is *withdrawn* in view of the amendment (10 February 2003, Paper No. 26).

The rejection of claims 4, 9, 11, 12 and 14 under 35 USC 112, second paragraph, as set forth at pages 6-7 of the previous Office Action (10 October 2002, Paper No. 24) is *withdrawn* in view of the amendment (10 February 2003, Paper No. 26).

The rejection of claims 1-4, 12 and 14 under 35 USC 102(e) as being anticipated by Takeshita *et al.*, US Patent 5,869,638 as set forth at pages 7-8 of the previous Office Action (10 October 2002, Paper No. 24) is *withdrawn* in view of the amendment (10 February 2003, Paper No. 26).

Claim Rejections - 35 USC § 102

Claims 19, 20, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Takeshita *et al.*, US Patent No. 5,869,638. The basis for this rejection is set forth at pages 7-8 of the previous Office Action (10 October 2002, Paper No. 24).

Applicant's arguments have been fully considered but not deemed persuasive for the following reasons. Applicant states that the allegation in the statement of the rejection (Office Action, page 8) that the sequence of Takeshita is 100% identical to the sequence i.e., SEQ ID NO:10, is not correct. This is not found to be persuasive. SEQ ID NO:10 consist of 26 residues, Takeshita teaches a sequence (from residue 26 to residue 51 of human OSF-4-1, SEQ ID NO:6), which is 100% identical to SEQ ID NO:10.

Applicant asserts that a person skilled in the art in view of Takeshita is not able to arrive at the subject matter of the presently claimed invention. Applicant maintains that a person skilled in the art has no incentive to prepare a fragment of OSF-4 of 26 amino acid residues. This is not found to be persuasive. Claim 19 is indefinite regarding open or closed language, the metes and bounds of the claim cannot be determined. Therefore, the Examiner has interpreted claim 19 as being drawn to open language.

Thus claim 19 does not necessarily read on a peptide "consisting of SEQ ID NO:10" (protein with only the 26 residues of SEQ ID NO:10). Claim 19 also reads on a protein "comprising SEQ ID NO:10" (protein with the 26 residues of SEQ ID NO:10, in addition to other residues).

Applicant contends that Takeshita teaches away from generating an active peptide fragment from the –terminus of OSF-4. Applicant states that according to the state of the art, the amino acids 26-51 were regarded as a pre-sequence, which is cleaved during the processing of the cadherin, and after cleavage is a non-functional waste product. Applicant directs Examiner's attention to figure 1 and table 4 in Takeshita *et al.* This is not found persuasive. It is unclear if Applicant is referring to another reference or Takeshita *et al.* by the statement "according to the state of the art". Table 4 of Takeshita *et al.* teaches the comparison of the amino acids among mouse OSF-4 and other cadherin molecules. Figure 1 depicts a schematic drawing of the structure of mouse OSF-4 precursor protein. Takeshita teaches that human OSF-4-1 (hOSF-4-1) encodes a protein consisting of 796 amino acids including a signal peptide composed of 24 amino acid residues (column 4, lines 51-54). Takeshita teaches the alignment of SEQ ID NO:6 in table 1. Contrary to Applicant's assertion, amino acids residues 26-51 of SEQ ID NO:6 (hOSF-4-1) are not part of the signal peptide.

Applicant states that the rejection is at least questionable in view of the statements made in the last Office Action and Office Action concerning unity of invention. Lastly, Applicant states that the Office Action relies on the allegation that a large protein does not inherently disclose a peptide and its activity, as stated on page 8.

line 6. This is not found persuasive. The Office Action concerning unity of invention was based on PCT Rules, which provide for examination of one product, one method of making the product and one method of using that product. Different sequences constitute different products, since they have diverse sequences, coding regions **and/or** impart structural and functional differences. The statement in the last Office Action concerned the generation of mutations, variants or fragments of SEQ ID NO:10. The protein of Takeshita *et al.* (SEQ ID NO:6, hOSF-4-1) **comprises** SEQ ID NO:10. In composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Furthermore, the preamble is generally nonlimiting if it merely recites an inherent property. See MPEP 2111.02. In the instant case, the claims read on a purified peptide sequence comprising SEQ ID NO:10. Takeshita discloses that OSF-4 is useful in the treatment of bone metabolic diseases (osteoporosis, osteomalacia) (column 1, lines 9-20). The prior art structure has all the features required to perform the intended use recited in the claims as Takeshita does not teach away from the intended use. More importantly, the instant specification does not provide a description of how SEQ ID NO:10 creates a tangible difference in the claimed composition and those in the art with compositions comprising SEQ ID NO:10 and the same intended use.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 101

Claim 26 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, First paragraph

Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for administering a medicament comprising SEQ ID NO:10 and auxiliary agents to promote cell proliferation of osteoblasts, does not reasonably provide enablement for a method for the treatment or prophylaxis of a degenerative or metabolic disease of the bones. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 4-6 of the previous Office Action (10 October 2002, Paper No. 24). Applicant contends that the claims are limited to subject matter in claim 12 considered enabled in accordance with the statement of rejection. This is not found to be persuasive. The last Office Action stated that the specification did not reasonably provide enablement for the claims as recited.

Claim 21 is drawn to a medicament containing a peptide (SEQ ID NO:10) together with auxiliary agents. Claim 24 is drawn to the use of the medicament according to claim 21 comprising administering the medicament to a person in need thereof for the treatment or prophylaxis of a degenerative or metabolic disease.

Prophylaxis means to completely stop a condition or disease from occurring. "Prophylaxis" is not a relative term, it is total. The specification is not enabled for a method of preventing or stopping a degenerative or metabolic bone disease. Furthermore, the specification has not taught how to treat degenerative or metabolic bone disease. Degenerative and metabolic bone diseases is a broad term which would encompasses many conditions and involve diverse factors such as genetics, environment, diet, etc. The specification only establishes that OB-CDGF (SEQ ID NO:10) has proliferative activity for osteoblasts. The specification fails to disclose a direct correlation (working examples, animal models, etc.) between the use of the instant invention and treatment in subjects for metabolic diseases of the bone such as osteoporosis, osteomalacia, or osteopenia.

The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections - 35 USC § 112, Second paragraph

Claim 19, 23, 26, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite because it is unclear whether the claim is drawn to a peptide sequence with open (comprising) or closed (consisting) language.

Claims 23, 26, 28 and 29 are improper Markush groups (MPEP 2173.05(h)). Amending the claims to recite "wherein" or "selecting from the group consisting of" would obviate the rejection.

Claim 26 provides for the use of the medicament according to claim 23 for the treatment and prophylaxis of degenerative and metabolic diseases of the bones, such as osteoporosis, osteomalacia and osteopenia, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding claim 26, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

RMD
April 30, 2003